

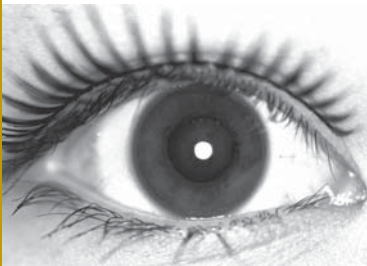
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FOCUS EYE CENTRE NEWSLETTER — FALL 2003 ■

Health Canada's view of laser vision correction

Federal government approves 'technology that improves lives', including Wavefront

There have been "tremendous strides" in laser vision correction (LVC) technology in the last 10 years that have resulted in impressive quality-of-life improvements, according to a medical officer on Health Canada's front lines.



Perhaps the most interesting advancement in LVC is Wavefront.

The speed of LVC technology's evolution goes hand-in-hand with computer technology's evolution, and the impact on people's lives is undeniably impressive, says Dr. Fred Lapner, section head of General and Restorative Devices of Health Canada's Medical Devices Bureau.

"When you consider that people — who have had to wear glasses their whole lives — can now get up in the night and see, go camping, or play sports without worrying about losing their glasses... it's obvious that technology can greatly improve people's lives."

Of course, the latest advancements demand serious scientific scrutiny before any new technology or technique makes it 'to market'.

Health Canada assures the safety and effectiveness of medical devices in Canada through a process of licensing, post market surveillance, and requirements for quality manufacturing. Manufacturers conducting clinical trials in Canada — which study new technology and/or new indications for use — require an authorization by the Medical Devices Bureau.

Prior to 1998, the excimer lasers used in LVC did not require a pre-market review for licensing. Under today's federal laws, they do, and the Bureau is the body responsible for administering the pre-market review requirements of Canadian Medical Devices Regulations.

Perhaps the most interesting advancement in LVC is Wavefront technology. Considered groundbreaking, Wavefront has the potential to improve not only how much you can see (visual acuity measured by the standard 20/20 eye chart), but also how well you can see (in terms of contrast sensitivity and fine detail). It allows for the creation of a three-dimensional (3-D) corneal map that reveals visual irregularities. That information — which is electronically transferred to the laser and computer-matched to the eye's position — allows LVC to be customized to each patient's unique requirements.

"We are very fortunate in Canada to have extremely well-trained and dedicated ophthalmologists involved in this research," says Dr. Lapner.

Asked how the LVC regulatory landscape in Canada compares to that in the U.S., Dr. Lapner notes the approval process in the two countries is "different, but the intention is identical" — namely, to ensure that the medical devices imported and sold in Canada "are safe and effective."

Patient profile

Emergency Measures:

Volunteer firefighter Elizabeth Greenberg enjoys benefits of LVC

These days, the job of a firefighter is more demanding than ever. So when Elizabeth Greenberg had the opportunity to free herself from glasses and contact lenses — serious impediments to battling a blaze — she took it.

"My decision to go for laser vision correction was almost entirely job-related," says Elizabeth. "I am a volunteer firefighter... [and] I was having problems with my glasses: having them slide down, steam up. They were just generally uncomfortable to wear."

Elizabeth often gets called in the middle of the night and must get dressed, get on the pumper and race to the scene of an emergency. Dealing with glasses or contact lenses made her job doubly

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Left to right: Jason Price, Kerry Harris, Elizabeth Greenberg and Trevor O'Grady (also a satisfied Focus Eye Centre patient).

Emergency Measures (cont.)

difficult. "[Fighting fires] is hard enough and stressful enough on its own; wearing glasses is one too many things to worry about."

The solution presented itself when a co-worker raved about the results he had achieved with laser vision correction done by Focus. "I had had friends who had it done and they were pleased with it... and they were all very excited about it... that kinda' spurred me on," she says.

So Elizabeth dropped in for a visit and was immediately impressed with the service — as well as the prospective outcome. "The staff instilled a lot of confidence in me. I didn't feel I had to look any further once I had been there for the consultation."

And, while she might take risks at work, Elizabeth wasn't about to take risk with her eyes. "I really wanted to see the man who would be doing the work on my eyes, and I didn't even have to ask." Dr. David Edmison entered the consultation room as a matter of course. Elizabeth liked what she saw and heard. "I felt comfortable letting him take care of something I consider very important: my eyesight."

Another concern was recovery time. But Elizabeth, who had the procedure in December of 2002, says this went better than she dreamed. "I had it done on Friday and I was in my fire vehicle answering calls on Monday."

Perhaps the greatest compliment, however, comes when Elizabeth, who had worn glasses from age 5, talks about her little girl. "My daughter, is 13 now... and I watch her struggling with her glasses. I have promised her that when she's old enough, I'll take her to Focus Eye Centre and put her eyes in their good hands."

Did You Know?

- Wavefront technology was originally developed for use in high power telescopes to reduce distortions when viewing objects in outer space.
- Wavefront identifies and measures the imperfections in an individual's eye 25 times more precisely than standard methods used for glasses and contact lenses.
- VISX excimer lasers have been used to successfully treat more than 3 million eyes in the United States and more than 5 million eyes globally.

Ask the Doctor

Q. What questions would you recommend a patient ask prior to undergoing laser vision correction?

A. There are, of course, many questions to ask before undergoing any medical procedure — and laser vision correction is no exception. Part of my job is educating patients and addressing any concerns they may have prior to surgery.

The most important questions are those relating to safety, efficacy and the results of laser vision correction. At Focus, the surgeon will try to cover all relevant questions that patients have relating to these issues. Not surprisingly, though, we get asked other questions that are not routine, such as:

- Are you the surgeon who will attend to me?
- What are the long term risks associated with LVC?
- Have any Focus patients experienced serious complications?
- Do you operate on both eyes the same day?
- How many operations have you, personally, performed?
- May I speak with any of your former patients?
- What anesthesia will I receive for the operation?
- How long will the procedure take?



Dr. David Edmison,
Medical Director,
Focus Eye Centre

A Web of Information

For more information about laser vision correction, Focus encourages you to visit the following websites.

- www.focuseye.com — Focus Eye Centre homepage
- www.hc-sc.gc.ca/english/iyh/medical/laser_eye.html — Health Canada's view of LVC
- www.allaboutvision.com — A wealth of info, including a page on vision surgery.
- www.eyeworld.org — Publication for eye care professionals and other industry insiders.
- www.ascrs.org — American Society of Cataract and Refractive Surgery
- www.visx.com — Website of leading manufacturer of laser technology
- www.isrs.org — International Society of Refractive Surgery



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